PB87-109419

Guidance for the Reregistration of Pesticide Products Containing Methamidophos as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

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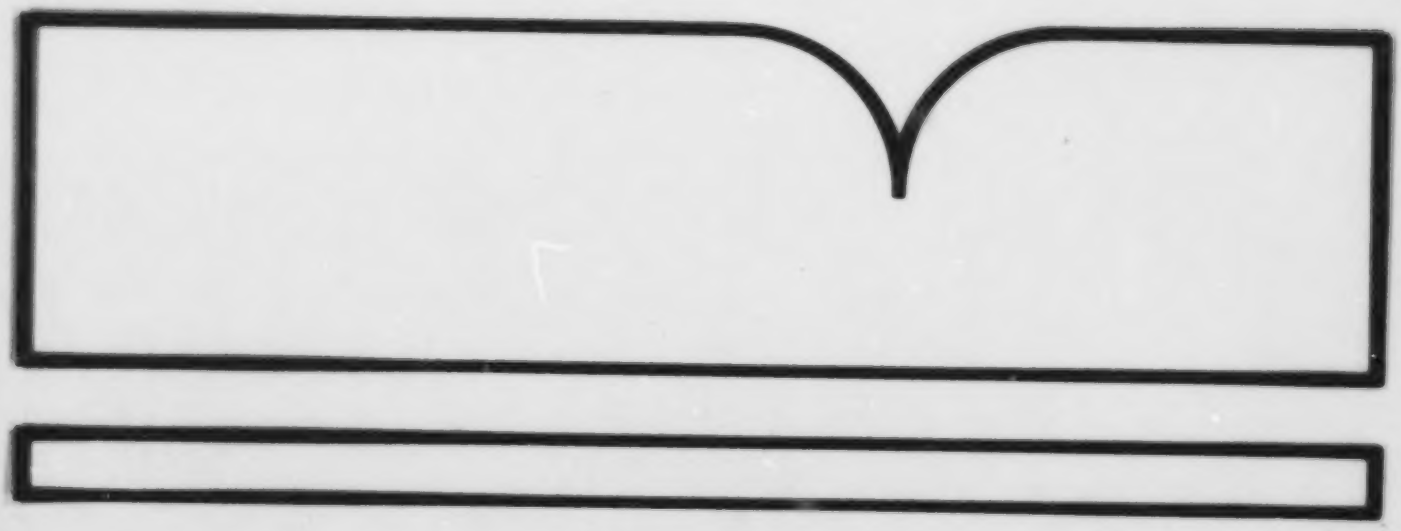

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This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GUIDANCE FOR THE

REREGISTRATION OF MANUFACTURING USE AND CERTAIN END USE PESTICIDE PRODUCTS

CONTAINING

METHAMIDOPHOS

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

WASHINGTON, D.C. 20460

SEPTEMBER 30, 1982

Table of Contents

Section		Page
I.	Introduction	1
II.	Regulatory Position	4
III.	Data Compensation	15
IV.	Submission of Generic Data under FIFRA	18
V.	Requirement for Submission of Product-Specific Data under FIFRA § (3)(c)(2)(B)	37
VI.	Submission of Revised Labeling and Packaging Information	40
	A. Label Contents	41
	1. Product Name	41
	2. Company Name and Address	41
	3. Net Contents	42

Table of Contents (Cont'd)

4. Product Registration Number. 42

5. Producing Establishment Registration Number 43

6A Ingredient Statement 43

6B Pounds per Gallon Statement. 43

7. Front Panel Precautionary Statements 43

7A Child Hazard Warning Statements. 44

7B Signal Word. 44

7C Skull and Crossbones and Word Poison 44

7D Statement of Practical Treatment 45

7E Referral Statement 45

8. Side/Back Panel Precautionary Labeling . . . 45

8A Hazard to Humans and Domestic Animals. . . . 46

8B Environmental Hazard 46

Table of Contents (Cont'd)

8C Physical or Chemical Hazard. 46

9 Misuse Statement 48

10A Storage and Disposal Block 48

10B Directions for Use 49

B. Collateral Information 49

VII. Instructions for Submission. 50

A. Manufacturing-use Products 50

B. End-use Products 50

APPENDICES

III-1(a) Data Compensation Statement: Reregistration (MUPs)

III-1(b) Data Compensation Statement: Reregistration (End-Use Products)

III-2(b) Product Specific Data Report (end-use products)

III-3 Bibliography

IV-2(a) FIFRA § 3(c)(2)(B) Summary Sheet

IV-3 Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data

VI-1 40 CFR § 162.10 Labeling Requirements

VI-2 Table of Labeling Requirements

VI-3 Physical-Chemical Hazards Labeling Statement

VI-5 Storage and Disposal Statements

Note: Appendices III-1, IV-1, IV-2, VI-4, and VI-6 are not germane to this document and are not included.

I. INTRODUCTION

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute that product in commerce must apply for reregistration.

This guidance document sets forth the requirements for registration and reregistration of all manufacturing use products (MUPs) containing the subject chemical as the sole active ingredient. These requirements are: that certain scientific data be submitted; that certain standards of toxicity, composition, labeling, and packaging be met; and that the data compensation provisions of FIFRA Section 3(c)(1)(D) be satisfied. Registrants of MUPs are referred to all Sections and Tables for specific information regarding their responsibilities under this guidance document.

This guidance document also sets forth the data requirements and compensation responsibilities for those end-use products which contain the subject active ingredient and for which the source of that active ingredient is (1) not registered with EPA or (2) produced by the registrant's firm, or a firm which has

ownership in common with the registrant's firm, or (3) both (1) and (2). Registrants of such end-use products can exempt themselves from these requirements if they change their source of supply to a registered source, provided the source (i.e. registered active ingredient product) is obtained from a firm that does not share ownership in common with the registrant's firm. (If the end-use product registrant decides to switch sources, a new confidential statement of formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this guidance document.) Registrants of affected end-use products are referred to only Sections II, III, IV and VII and Table A for specific information regarding their responsibilities under this guidance document.

It should be noted that end-use products containing the subject active ingredient will not be reregistered at this time. Any necessary labeling changes will be implemented under the Agency's Label Improvement Program at a future time.

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if the registrant fails to comply with the requirements set forth in this guidance document.

This guidance document has been prepared to provide registrants with specific information on how they may reregister their manufacturing-use products or maintain their end-use products' registration. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time frames outlined.

II. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This chapter describes the regulatory position of the Environmental Protection Agency ("the agency") on Methamidophos, based on an evaluation of all registered, manufacturing-use products (MUP's) containing methamidophos as the sole active ingredient. There are no current registrations that include methamidophos in mixtures. Future requests for registrations of substantially similar products (either single-active-ingredient or mixtures) will be covered by this Standard. Dissimilar products will require amendments to the standard. This document provides the rationale for the agency's position and the criteria for registration that result from it. It also discusses labeling requirements and tolerances. Finally, it considers "Special Local Needs" registrations, authorized by Section 24(c) of the FIFRA in addition to federal registrations granted or pending under Section 3 of the FIFRA.

B. USE PROFILE

Methamidophos is the common name for O,S-dimethyl phosphoramidothioate, marketed in this country by the Chevron and Chemagro companies, under the trade name Monitor®. It is an organophosphorous compound which controls a broad spectrum of insects through contact and systemic action. It is used principally on potatoes, cotton, and cole crops and is applied both aerially and with ground spray equipment. The principal pests controlled on potatoes are aphids, cabbage looper, Colorado potato beetle, flea beetles, leafhoppers,

and potato tuberworms. Lygus bugs are the main target pests on cotton ; and cabbage looper, diamondback moth (larvae), and imported cabbageworm are the pests controlled on cabbage and other cole crops.

There are two Federal registrations for MUP's: Ortho Chevron Monitor® Technical and Monitor® Technical. Both contain 72 percent methamidophos active ingredient. There are three emulsifiable concentrate end-use products with Federal registrations: Chevron Ortho Monitor® 4 Spray; Chevron Ortho Monitor® 6 Spray; and Chemagro Monitor® 4 Liquid Insecticide. There are also several "Special Local Needs" registrations.

Tolerances have been established for the following raw agricultural commodities: broccoli, brussels sprouts, cabbage, cauliflower, cottonseed, cucumber, eggplant, lettuce, melons, peppers, potatoes, sugar beet roots and tops, and tomatoes. Residues of methamidophos are also allowed in tolerances for acephate (Orthene®), a structurally similar insecticide that is contaminated with and degrades into methamidophos. Those tolerances will be discussed in the Registration Standard on that compound.

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on methamidophos, the Environmental Protection Agency has made the following determinations:

1. Manufacturing-use pesticide products containing methamidophos as a sole active ingredient or mixed with other active ingredients may be registered for sale, distribution, and use, subject to the terms and conditions specified in this standard.

2. Available data do not show that any of the risk criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of methamidophos specified in this standard.

3. Registrants must provide or agree to develop additional data, as specified in the tables attached to this standard, in order to maintain existing registrations or to permit new methamidophos registrations.

4. Tolerance reassessment is normally a part of the Registration Standard review process. The agency will be unable to complete its reassessment of this compound, though, because essential toxicology tests are not yet available. Specifically, the agency is not able to

establish a valid "No Observable Effect Level" (NOEL) or determine an "Acceptable Daily Intake" (ADI) for methamidophos. No further permanent tolerances will be granted until the toxicology data gaps are filled.

D. REGULATORY RATIONALE

The agency has determined that it should continue to allow the registration of methamidophos for the following reasons:

1. All liquid formulations of Methamidophos containing 40 per cent or more active ingredient (a.i.) have been classified for Restricted Use (use only by, or under the supervision of, certified applicators). That classification, together with stringent label precautions (including requirements for protective clothing), will minimize the acute hazards associated with dermal, oral, and inhalation exposure.

2. No toxicological hazards of concern have been identified in the studies reviewed for this standard.

3. Existing evidence does not suggest that current tolerances would result in residue levels that will expose the public to unreasonable adverse effects.

4. Methamidophos is not expected to leach or run off into drinking water supplies. However, current data are inadequate to confirm this expectation; therefore further environmental fate testing is required.

5. Label warnings required by this standard should protect fish and wildlife from known hazards. However, the hazards to birds or aquatic invertebrates (or both) may be greater than previously supposed. These questions will be resolved by studies required by this standard.

6. Available data on both human and wildlife poisoning incidents indicate that the majority of cases of human poisoning cited in the Pesticide Incident Monitoring System (PIMS) through August of 1979 appeared to be the result of misuse or accident. It is not as clear, however, whether nontarget wildlife-related incidents were also unavoidable or were the result of normal use. The agency will not be able to resolve this question until reentry and wildlife data required by this standard are submitted.

7. It is not the agency's policy to cancel or to withhold registration merely because data are missing or inadequate (See Sections 3(c)(2)(B) and 3(c)(7) of the FIFRA). Rather, publication of this standard provides a mechanism for identifying data needs and registration under the standard allows for the upgrading of labels during the period in which the required data are being developed. These data will be reviewed and evaluated when they are received and the agency will determine, at that time whether they will affect the registration(s) of methamidophos.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To be covered by this standard, products must:

- Contain methamidophos as the sole active ingredient or in combination with other active ingredients in a mixture,
- Bear required labeling, and
- Conform to the acute toxicity limits, product composition, and use pattern requirements listed in Section F of this document.

The applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in it. That includes making a commitment to fill data gaps on a schedule agreed to by both this agency and the applicant. Applicants must also indicate a willingness to pay compensation for data to the extent required by Section 3(c)(1)(D) of the FIFRA. Applicants for registration under this standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be covered under this standard, technical grade products must contain at least 72 percent methamidophos as the sole active ingredient. Each

manufacturing-use product formulation proposed for registration must be fully described with an appropriate certification of limits.

2. Acute Toxicity Limits

The agency will consider registration of technical grade and manufacturing-use products containing methamidophos for acute toxicity category I, II, III, or IV provided that the labeling of those products bears appropriate precautionary statements.

3. Use Patterns

To be registered under this standard, manufacturing-use products containing methamidophos may be labeled for formulation only into end-use products for use on broccoli, brussels sprouts, cabbage, cauliflower, cotton, potatoes, cucumbers, eggplant, lettuce, melons, peppers, sugar beets, tomatoes, and seed crops of alfalfa, carrots, clover, sugar beets, and table beets. The last eleven crops listed are currently registered under Section 24(c) of the FIFRA, as amended.

End-use products formulated from products registered under this standard must be emulsifiable concentrate formulations, for aerial or ground spray application.

G. REQUIRED LABELING

All technical grade, manufacturing-use, and end-use products containing methamidophos must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements.

The labels of all manufacturing-use products must contain the statement "For formulation into end-use, insecticide products intended only for non-domestic, outdoor use on [crops to be specified]."

All end-use liquid formulations containing 40 per cent methamidophos or more will continue to be classified as "Restricted Use" pesticides and all labels must reflect that classification.

Labels for all products containing methamidophos must continue to bear warning statements reflecting the acute human toxicity of the compound and its dermal absorption characteristics. "Environmental Hazards" warnings must also remain on all labels.

For all manufacturing-use products, the following statement must be added to the label:

> " This product is extremely toxic to birds and other wildlife. Do not discharge into lakes, streams, ponds, or public waters except in accordance with a NPDES permit. For further guidance, contact the nearest EPA Regional Office."

H. TOLERANCE REASSESSMENT

Methamidophos has been accepted for use on several crops and tolerances have been issued (40 CFR 180.315) for residues of the compound in those crops. The general data base supporting those tolerances is not complete, however, and no further tolerances can be granted until it is. Specific residue data are still missing for some crops and must be provided to the agency. Several chronic tests that were originally performed by the Industrial Bio-Test laboratories (IBT) have been found to be invalid and must be replaced. Details on all tolerance-supporting data requirements are provided in the accompanying tables. The agency will reassess all methamidophos tolerances (including those associated with acephate (Orthene®) registrations) when the necessary toxicology and residue data are received.

The established tolerances for broccoli, cabbage, cottonseed, lettuce, melons (ground spray application), potatoes, and sugar beets (including seed crops) are supported by adequate residue data. However, additional residue data are required to support established tolerances for: brussels sprouts, cucumbers, melons (aerial application), cauliflower, eggplant, tomatoes, lettuce, and peppers. Additional residue data are also needed for processed peppers and dehydrated tomatoes.

Residue data are being required for alfalfa and clover grown for their seed because cuttings might be made for feed use and germinating alfalfa seeds (sprouts) are used for human food. Residue data are required for carrots and table (garden) beets grown for their seed because roots and tops (of beets only) may be fed to livestock. Residue data are also being required on carrots and table beets grown from the seed of previously treated crops.

Available data on residues in the processed products of cottonseed (oil, hulls, and meal) and of all sugar beet root products indicate that no food additive tolerances need be established for these products. No additional animal feeding studies are being required for two reasons. First, available evidence indicates that residues of methamidophos are very low in by-product feed items. Second, the current acephate tolerances (for combined residues of acephate and methamidophos) in meat, milk, poultry, and eggs are adequate to cover any secondary residues of methamidophos occurring in these commodities

resulting from the current uses of methamidophos for which tolerances have been established (in feeds of cotton by-products; sugar beet tops and by-products; and tomato by-products).

Applicants seeking registration of methamidophos on additional food or feed sites must submit data which support the establishment of a new tolerance or which justify an exemption on the grounds that no residues will be present.

III. DATA COMPENSATION

As part of your application for reregistration, you must comply with the data requirements of FIFRA Section 3(c)(1)(D) by including with your application a completed Data Compensation Statement (Appendix III-1). That form includes:

A. A statement that you offer to pay compensation to other persons with regard to the application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D).

B. A statement acknowledging that if EPA approves your application for registration, the approval will be based on EPA's consideration of the following:

1. All the existing "generic" data* which, according to the table, "Generic Data Requirements for Manufacturing Use and End Use Products" (Table A at the end of Section IV), is relevant to EPA's evaluation of the registrability of your product.

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*/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2. For the manufacturing use products, the "product-specific" data* which you have listed on the form entitled "Product-Specific Data Report" (Appendix III-2).

C. A statement that you have furnished an offer to pay compensation to the person(s) listed below in the manner specified:

1. Persons to whom offers must be made: An offer must be furnished to each person who was the original submitter of any of the generic or product specific data upon which approval of your application will be based, except that:

a. You need not furnish an offer with respect to data that were originally submitted prior to January 1, 1970.

b. Many data submitters have informed EPA that they do not wish to receive offers under FIFRA Section 3(c)(1)(D). The various persons who submitted data listed in the bibliography

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*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

(Appendix III-3) who have not waived their rights to receive offers will be listed in Tables A and B (MUP registrants are referred to both Tables A & B; end-use product registrants are referred to only Table A). You will be required to write the companies listed in the appropriate table(s) if the data in those tables are required to support your formulations and/or uses.

c. You need not furnish an offer to any person with whom you have already agreed in writing concerning the amount (if any) and terms of compensation payable under FIFRA Section 3(c)(1)(D) in connection with the reregistration of your product.

d. You need not furnish an offer with respect to any data unless the data were submitted to EPA (or its predecessor agencies) to support an application for registration, amended registration, or reregistration; to support or maintain in effect an existing registration; to support an application for an experimental use permit; or to support a petition for a tolerance, food additive regulation, or other clearance under the Federal Food, Drug and

Cosmetic Act which was a prerequisite to a FIFRA registration action.

2. Form of the offer: You must furnish each person who is entitled to receive an offer the following information, in writing:

a. A notification of your intent to apply for registration or reregistration under this guidance document, and the name, active ingredient, and intended uses of your product.

b. An offer to pay the person compensation with respect to approval of your application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D), and an offer to begin negotiations to set the amount and terms of compensation.

c. Your name, mailing address, and telephone number.

IV. REQUIREMENT FOR SUBMISSION OF GENERIC DATA UNDER FIFRA SECTION 3(c)(2)(B)

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section

3(c)(2)(B). EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA approved protocols, The

Pesticide Registration Guidelines,*/ or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally Ecological Effects), EPA requires the test substance to be a "typical formulation," and that in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.). These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Section V of this document.

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*/ The Pesticide Registration Guidelines were proposed in two separate publications. On July 10, 1978, EPA issued proposed guidelines for product chemistry, environmental chemistry, and fish and wildlife hazard testing, 43 FR 29696. The Agency published proposed human hazard guidelines on August 22, 1978, 43 FR 37336.

TABLE A-1

[illegible]

Data Requirements: PRODUCT CHEMISTRY *

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? **
163.61-3	Product Identity and Disclosure of Ingredients	Technical Grade (TG)	yes	00014037 A/	no 1/
163.61-4	Description of Manufacturing Process	TG	partially	00014024 A/	yes 1/ 2/
163.61-5	Discussion of Formation of Unintentional Ingredients	TG	yes	00014024 A/	no 1/
163.61-6	Declaration & Certification of Ingredients Limits	TG	partially	00014024 A/	yes 1/ 3/
163.61-7	Product Analytical methods and data	TG	partially	00014023, A/ 00014025 to 00014030 A/ 00014032, 00014033 A/	yes 1/ 4/
163.64-2	Color	TG	yes	00014021 A/	no
163.64-3	Physical State	TG	yes	00014021 A/	no
163.64-4	Odor	TG	yes	00014021 A/	no
163.64-5	Melting Point	TG	no	—	yes
163.64-7	Density / Specific Gravity	TG	yes	00014021 A/	no
163.64-8	Solubility	TG	yes	00014021 A/	no
163.64-9	Vapor Pressure	Analytical Grade	yes	00014021 A/	no
163.64-12	pH	TG	no	—	yes
163.64-13	Stability	TG	no	—	yes
163.64-14	Oxidation/ Reduction	TG	no	—	yes
163.64-17	Storage Stability	TG	no	—	yes
163.64-20	Corrosiveness	TG	yes	00014021 A/	no

* All requirements apply to registrations for "Non-domestic, terrestrial, food crop" uses, only.

** All data must be submitted within 6 months (due March'83).

Footnotes

1. These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. References cited are applicable only to the currently registered technical product.

2. Further information is necessary on starting and intermediate materials and descriptions of quality control measures.

3. A declaration and certification of ingredients must be provided.

4. Existing submissions contain insufficient information on analytical methods (and their detection limits) for identifying methemidophos in formulations.

A. Studies submitted by Chevron Chemical Company. These studies may be compensable.

B. Studies submitted by Mobay Chemical Corporation. These studies may be compensable.

C. These studies may be compensable.

TABLE A-2

METHAMIDOPHOS

Generic Data Requirements: ENVIRONMENTAL FATE *

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? **
163.161-1	Hydrolysis	Radiolabeled analytical grade or non-labeled technical grade	no	-	yes
163.161-2	Photodegradation in Water	-SAME-	no	-	yes
163.161-3	Photodegradation in Soil	-SAME-	no	-	yes
163.161-4	Photodegradation in Air	-SAME-	no	-	RESERVED 1/
163.162-1	Aerobic Soil Metabolism	-SAME-	yes	00014976, A/ 00014497 A/ 00014991, A/ 05017379 C/	no 2/
163.162-2	Anaerobic Soil Metabolism	-SAME-	Partially	00014976 A/	yes 3/
Reserved	Effects of the Compound on Microbes, Effects of Microbes on the Compound, or Both	-SAME-	no	-	RESERVED 4/
163.163-1	Leaching	-SAME-	Partially	00014992, A/ 00029987 A/	yes 5/
163.163-2	Laboratory Volatility	Typical end-use product of major formulation category	no	-	yes 6/
163.163-3	Field Volatility	-SAME-	no	-	RESERVED 7/

* All requirements apply to registrations for "Non-domestic, terrestrial, food crop" uses, only. Registration for other use patterns may involve different data requirements.

** All data must be submitted within 36 months (due September '85).

TABLE A-2 (Page 2.

METHANIDOPHOS

Generic Data Requirements: ENVIRONMENTAL FATE *

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? **
163.164-1	Field Dissipation-Terrestrial	Typical end-use product of major formulation category	yes	00014076 A/, 00014497 A/ 00014991 A/, 05017379 C/	no
163.164-5	Dissipation-Long Term Studies	-SAME-	yes	00014076 A/, 00014497, A/ 00014991 A/, 05017379 C/	no
163.165-1	Confined Accumulation-Rotational Crops	Radiolabeled analytical grade	no	—	yes
163.165-2	Field Accumulation-Rotational Crops	Typical end-use product of major formulation category	no	—	Reserved B/
163.165-4	Fish Accumulation-Laboratory Studies	Radiolabeled analytical grade or non-labeled technical grade	yes	00014014 A/, 00014017 A/ 00014018 A/, 00014019 A/	no
163.165-5	Field Accumulation-Aquatic Non-Target	Typical end-use product of major formulation category	yes	00014496 A/, 00015242 A/	no
Subpart K	Reentry	-SAME-	no	-	yes B/

* All requirements apply to registrations for "Non-domestic, terrestrial, food crop" uses, only. Registration for other use patterns may involve different data requirements.

** All data must be submitted within 36 months (due September '85).

FOOTNOTES

1. Reserved, depending on data derived from volatility studies required under Section 163.163-2.

2. Cited studies were not conducted to the precise letter of Guidelines requirements. When considered together, though, they fill the agency's needs, particularly in view of the very rapid aerobic soil metabolism of methamidophos.

3. Duration of referenced study was not sufficient to establish a decline curve or half-life. It also failed to identify residues remaining under anaerobic conditions.

4. The requirement for these tests is being reserved pending the development or modification of testing protocols.

5. A degradate mobility study, using aged residues as described in Section 163.163-1, is needed to assess the leaching potential of degradation products.

6. Test substance should be an emulsifiable concentrate formulation.

7. Reserved, depending on data derived from laboratory volatility tests under Section 163.163-2.

8. Required only when significant C^{14} residues are found in Section 163.165-1 tests; or when subsequent crop is treated with same compound as initial crop.

9. The registrant must propose an acceptable reentry level for each crop. The proposed interval may be based on any of the following kinds of data:

   a. The longest reentry intervals currently accepted for this compound by this agency;

   b. Data on dissipation of foliar residues (decline curve), considering human exposure to those residues and the inherent toxicity of the chemical;

   c. Precise determination of that time beyond which there are no detectable foliar residues, considering the places where the chemical will be applied and the climatic conditions common to those areas.

Either the most restrictive reentry interval currently accepted or the exposure data and a dislodgeable residue curve (together with data on the toxicity of methamidophos) may be used to establish a proposed interval for activities that result in foliar contact. The longest intervals will be listed by crop.

A. Studies submitted by Chevron Chemical Company. These studies may be compensable.

B. Studies submitted by Mobay Chemical Corporation. These studies may be compensable.

C. These studies may be compensable.

TABLE A-3

METHAMIDOPHOS

Generic Data Requirements: TOXICITY *

Guideline Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? **
163.81-1	Acute Oral Toxicity	Technical Grade (TG)	yes	00014044[A], 00014045[A], 00014047[A], 00014048[A]	no
163.81-2	Acute Dermal Toxicity	TG	yes	00014049[A]	no
163.81-3	Acute Inhalation Toxicity	TG	Partially	00014051[A]	yes 1/
163.81-4	Primary Eye Irritation	TG	yes	00014221[A]	no
163.81-5	Primary Dermal Irritation	TG	yes	00014220[A]	no
163.81-6	Dermal Sensitization	TG	no	—	yes
163.81-7	Acute Delayed Neurotoxicity	TG	yes	00041317[A]	no
163.82-1	Subchronic Oral Toxicity	TG	Partially	00014153[A], 00014155[A]	no 2/
163.82-2	21-Day Subchronic Dermal Toxicity	TG	no	—	yes
163.82-3	90-Day Subchronic Dermal Toxicity	TG	no	—	no 3/
163.82-4	Subchronic Inhalation Toxicity	TG	no	—	no 4/
163.82-5	Subchronic Neurotoxicity	TG	no	—	no 5/
163.83-1	Chronic Feeding	TG	no	—	yes 6/
163.83-2	Oncogenicity	TG	Partially	GR0043-001[A]	yes 6/
163.83-3	Teratogenicity	TG	Partially	00041315[A]	yes 6/ 7/
163.83-4	Reproduction	TG	no	—	yes 6/
163.84-2 through -4	Mutagenicity	TG	no	-	yes 6/ 8/
163.85-1	Metabolism (Identification of Metabolites)	Radiolabeled, Analytically Pure Grade of A.I.	yes	00015224[A], 00014518[A], 00015222[A]	no

* All requirements apply to registrations for "Non-domestic, terrestrial, food crop" uses, only. Registration for other use patterns may involve different data requirements.

** All data must be submitted within 36 months(due September'85) except 163.81-3, 163.81-6 and 16382-2 which are due March'83.

1. The available data are incomplete. In the study cited, the concentration of the test material and the size of the particles in the inhalation chamber were unknown. Also, because there was no mortality among the test animals, the LC_{50} was not determined.

2. Two 90-day studies (dog and rat) are available but both are incomplete (supplementary). One study tested only two dogs per sex per dose and neither study included histopathological evaluation. However, because two chronic feeding studies (rat and dog) have been requested, the 90-day rat and dog feeding studies will not be required.

3. This study is not required because the pesticidal uses of methamidophos exclude swimming pools and fabrics and do not involve intentional application to the skin.

4. This study is not required. Although the results of acute inhalation testing are incomplete and the LC_{50} was not determined, it is unlikely that the pesticidal use of methamidophos technical will involve repeated inhalation exposure to toxic levels of the compound.

5. This test is not required because the results of the acute delayed neurotoxicity test were negative.

6. According to the Mobay Chemical Corporation, these studies will be completed during the next two years as follows:

STUDY	ESTIMATED COMPLETION DATE
Chronic, oncogenic, rat	August, 1984
Oncogenic, mouse	January, 1981
Teratology, rat	October, 1982
Mutagenic, Ames	February, 1982
Mutagenic, dominant lethal	January, 1983
Reproductive, rat	June, 1984

A chronic (at least 12 months) dog feeding study has also been required, but its completion date is unknown.

7. Two teratology studies are required, but only one (rabbit) test is currently available.

8. For each test substance a battery of tests is required to assess the potential to affect the qualitative or quantitative integrity of the mammalian cell's genetic components. The objectives underlying the selection of a battery of tests for mutagenicity assessments are:
   1) to detect, with sensitive assay methods, the capacity of a chemical to alter genetic material;
   2) to determine the relevance of these mutagenic changes to mammals, and when mutagenic potential is demonstrated;
   3) to incorporate these findings in the assessment of heritable effects, oncogenicity, and possibly, other toxic endpoints.

   Tests Required. The battery must include tests appropriate to address the following three categories:
   1) gene mutations
   2) structural chromosomal aberrations
   3) other genotoxic effects as appropriate for the test substance, e.g., numerical chromosome aberrations, direct DNA damage and repair.

A. Studies submitted by Chevron Chemical Company. These studies may be compensable.

B. Studies submitted by Mobay Chemical Corporation. These studies may be compensable.

C. These studies may be compensable.

TABLE A-4

METHAMIDOPHOS

Generic Data Requirements: RESIDUE CHEMISTRY *

Guideline Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? **
-	Metabolism in Plants	Representative Formulation	yes	00014081 A/, 00014077 A/	no
-	Metabolism in Animals	Representative Formulation	yes	00014995 A/, 00014555 A/ 00015222 A/	no
-	Analytical Methods	Representative Formulation	yes	00014085 A/	no
-	Residue Data: Crops-	Representative Formulation			
-	Broccoli		yes	00014069 A/	no
-	Brussels Sprouts		partially	00014070 A/	yes 1/
-	Cabbage		partially	00014071 A/	yes 2/
-	Cauliflower		partially	00014072 A/	yes 3/
-	Cotton		yes	00014074 A/	no
-	Cucumbers		partially	00014132 A/, 00014133 A/ 00014138 A/, 00014139 A/	yes 1/
-	Eggplant		partially	00014119 A/, 00014120 A/ 00014130 A/, 00014131 A/	yes 4/
-	Lettuce		partially	00014073 A/	yes 5/
-	Melons		partially	00014134 A/, 00014135 A/	yes 1/
-	Peppers		partially	00014121 A/, 00014122 A/ 00014123 A/, 00014140 A/	yes 6/
-	Potatoes		yes	00014075 A/	no

* All requirements apply to registrations for "Non-domestic, terrestrial, food crop" uses, only. Registration for other use patterns may involve different data requirements.

** All data must be submitted within 36 months. (due September'85).

TABLE A-4 (Page 2)

METHAMIDOPHOS

Generic Data Requirements: RESIDUE CHEMISTRY *

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? **
-	Sugar Beets		yes	00014269 [R], 00014268 [R], 00014272 [R]	no
-	Tomatoes		partially	00014124 thru 00014129 [R]	yes 7/
-	Crops Grown for Seed	Representative Formulation	partially	00014269 [R], 00014268 [R], 00014272 [R]	yes 8/
-	Residue Data: Processed Commodities	Representative Formulation	no		yes 9/
-	Residue Data: Meat, Milk, Poultry, and Eggs	Representative Formulation	yes	00015183 [R], 00015225 [R]	no

* All requirements apply to registrations for "Non-domestic, terrestrial, food crop" uses, only. Registration for other use patterns may involve different data requirements.

** All data must be submitted within 36 months.

REMARKS

1. Either residue data for aerial applications are needed or labels must be modified to prohibit aerial application.

2. Data describing residue levels in outer leaves are required because these leaves are used (as wrapping) during the transportation of a commodity in interstate commerce.

3. The available residue data for cauliflower do not support the established tolerance because application methods were not specified. Existing petitions must be supplemented with this information or the data must be replaced.

4. For tolerances on eggplant grown in Mexico, information on the application methods used in developing data previously submitted is not available. It must be submitted or the studies must be repeated and resubmitted. Data reflecting the use of the maximum application rate (1 lb. a.i. per acre) must also be submitted to support current tolerances for eggplant grown in the U.S.

5. Current data do not adequately support the established tolerance because they do not describe residues on head lettuce with most or all of the wrapper leaves intact (as it is typically transported in interstate commerce). These data must be supplemented or replaced.

6. .rent data do not support the tolerance for use of methamidophos on peppers in Mexico. One of three samples exceeded the tolerance 14 days after the last application (the current preharvest interval is 14 days) and the maximum seasonal rate was not applied. Because current data show that residue levels fall to (or below) tolerance levels by 21 days after the last application, either an extension of the labeled PHI to 21 days or data on the period between day 14 and day 21 will be accepted to fill this gap. New studies that reflect the maximum permitted application rate must also be submitted, or labels must be modified to reflect the maximum rate tested.

7. In order to support the established U.S. tolerance, data must be submitted from studies using the maximum application rate allowed by current labels, 1 lb. a.i. per acre, or the maximum label rate must be reduced to the level tested (.5 lb. a.i. per acre).

8. a. No additional residue data are needed for sugar beets because residues for that crop are already covered by the established tolerances for roots and tops.

   b. Residue data are needed for alfalfa and clover grown for their seed because cuttings might be sold for feed use and because germinating alfalfa seeds (sprouts) are used by humans for food.

   c. Residue data are needed for carrots and table (garden) beets grown for their seed because roots and tops (of beets only) may be fed to livestock. In addition, residue data will be needed on carrots and table beets grown from the seed of previously treated crops.

9. Residue data are needed for the processed products of peppers and tomatoes that require dehydration of the raw agricultural commodity.

A. Studies submitted by Chevron Chemical Company. These studies may be compensable.

B. Studies submitted by Mobay Chemical Corporation. These studies may be compensable.

C. These studies may be compensable.

TABLE A-5

REGISTRATION

Generic Data Requirements: ECOLOGICAL EFFECTS *

Guideline Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? **
163.71-1	Avian Single-Dose Oral LD_{50}	Technical Grade (TG)	yes	00041313 [B], 00014094 [A], 00014095 [A], 00041-001 [C]	no
163.71-2	Avian Dietary LC_{50}	TG	yes	00041-002 [C], 00041658 [B], 00014064 [A], 00014304 [B]	no
163.71-4	Avian Reproduction	TG	yes	00014111 [A], 00014114 [A]	no
163.71-5	Simulated/Actual Field Testing for Mammals and Birds	End-use Formulation (Monitor 6 Spray) 1/	no	--	yes 2/
163.72-1	Fish Acute LC_{50}	TG	yes	00041312 [B], 00014063 [A]	no
163.72-2	Acute Toxicity to Aquatic Invertebrates	TG	yes	00041311 [B], 00014110 [A], 00014305 [B]	no
163.72-3	Acute Toxicity to Estuarine & Marine Organisms	TG	no	--	yes 3/

* All requirements apply to registrations for "Non-domestic, terrestrial, food crop" uses, only. Registration for other use patterns may involve different data requirements.

** All data must be submitted within 16 months (due September '85).

[redacted]

1. This formulation was selected because it has the highest active ingredient concentration of currently registered formulations.

2. A short-term (small pen) simulated field study on birds using an end-use product is required when the use of the product is likely to result in adverse effects on avian wildlife exposed to the pesticide. Three registered end-use products (Monitor 4 Spray, Monitor 6 Spray, and Monitor 4) can be used on cotton, potatoes, and vegetable crops at rates (1 lb. active ingredient per acre) that will very likely have adverse effects on birds. The maximum calculated residues on avian food items (ppm) and the calculated amount of toxicant that different size birds might be exposed to in their diets (mg/kg) are, in many cases, greater than the laboratory acute (LD_{50}) and subacute (LC_{50}) toxicity levels. In addition, a 1980 bird kill in Wisconsin was reported to be the result of an aerial application of Monitor 4 to cabbage.

3. Testing is required to establish the acute toxicity of the technical pesticide to estuarine or marine invertebrates when the end-use product is expected to enter the estuarine or marine environment in significant concentrations because of its use or mobility pattern. In the case of methamidophos, it is very soluble in water and mobile in the soil and it is used on cotton and on vegetable crops in Florida and other Gulf coastal states adjacent to aquatic estuarine and marine habitat.

A. Studies submitted by Chevron Chemical Company. These studies may be compensable.

B. Studies submitted by Mobay Chemical Corporation. These studies may be compensable.

C. These studies may be compensable.

TABLE A-1

PESTICIDES

Product-Specific, Manufacturing-Use Data Requirements: PRODUCT CHEMISTRY * **

Guidelines Citation	Name of Test	Composition	Does EPA have data to p rtially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? ***
163.61-3	Product Identity and Disclosure of Ingredients	Each Product	yes	00014024[A], 00014037[A]	no [1]
163.61-4	Description of Manufacturing Process	Each Product	partially	00014024[A]	yes [1] [2]
163.61-5	Discussion of Formation of Unintentional Ingredients	Each Product	yes	00014024[A]	no [1]
163.61-6	Declaration & Certification of Ingredients Limits	Each Product	partially	00014024[A]	yes [1] [3]
163.61-7	Product Analytical methods and data	Each Product	partially	00014023,[A] 00014025 to 00014030,[A] 00014032, 00014033[A]	yes [1] [4]
163.64-2	Color	Each Product	yes	00014021[A]	no
163.64-3	Physical State	Each Product	yes	00014021[A]	no
163.64-4	Odor	Each Product	yes	00014021[A]	no
163.64-5	Melting Point	Each Product	no	—	yes
163.64-7	Density / Specific Gravity	Each Product	yes	00014021[A]	no
163.64-8	Solubility	Each Product	yes	00014021[A]	no
163.64-9	Vapor Pressure	Analytical Grade	yes	00014021[A]	no
163.64-12	pH	Each Product	no	—	yes
163.64-13	Stability	Each Product	no	—	yes
—	Oxidizing/reducing	Each Product	no	—	yes
—	Explosiveness	Each Product	no	—	yes
—	Corrosion Characteristics	Each Product	yes	00014021[A]	no

* All requirements apply to registrations for "Non-domestic, terrestrial, food crop" uses, only. Registration for other use patterns may involve different data requirements.

** Cited data will be applicable to new registration requests only when requests are for MUP's judged to be "substantially similar" to currently registered products.

*** All data must be submitted within 6 months (due March'83).

FOOTNOTES

1. These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. References cited are applicable only to the currently registered manufacturing-use products.

2. Further information is necessary on starting and intermediate materials and descriptions of quality control measures.

3. A declaration and certification of ingredients must be provided.

4. Existing submissions contain insufficient information on analytical methods (and their detection limits) for identifying methamidophos in formulations.

A. Studies submitted by Chevron Chemical Company. These studies may be compensable.

B. Studies submitted by Mobay Chemical Corporation. These studies may be compensable.

C. These studies may be compensable.

TABLE A-2

METHAMIDOPHOS

Product-Specific, Manufacturing-Use Data Requirements: TOXICOLOGY * **

Guidelines Citation	Name of Test	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? ***
163.81-1	Acute Oral Toxicity	Each Product	yes	00014044[A], 00014045[A], 00014047[A], 00014048[A]	no
163.81-2	Acute Dermal Toxicity	Each Product	yes	00014049[A]	no
163.81-3	Acute Inhalation Toxicity	Each Product	partially	00014051[A]	yes [1]
163.81-4	Primary Eye Irritation	Each Product	yes	00014221[A]	no
163.81-5	Primary Dermal Irritation	Each Product	yes	00014220[A], 00014222[A]	no
163.81-6	Dermal Sensitization	Each Product	no	—	yes

* All requirements apply to registrations for "Non-domestic, terrestrial, food crop" uses, only. Registration for other use patterns may involve different data requirements.

** Cited data will be applicable to new registration requests only when requests are for MUP's judged to be "substantially similar" to currently registered products.

*** All data must be submitted within 6 months (due March'83).

FOOTNOTES

1. The available data are incomplete. In the study cited, the concentration of the test material and the size of the particles in the inhalation chamber were unknown. Also, because there was no mortality among the test animals, the LC_{50} was not determined.

A. Studies submitted by Chevron Chemical Company. These studies may be compensable.

B. Studies submitted by Mobay Chemical Corporation. These studies may be compensable.

C. These studies may be compensable.

C. Options Available for Complying with Requirements to Submit Data.

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA § 3(c)(2)(B) Summary Sheet" [Appendix IV-2(a)] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" (Appendix IV-3*/.

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement between all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)], and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should

state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

V. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA UNDER FIFRA § 3(c)(2)(B)

Note: This section applies only to manufacturing use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B) EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than 6 months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under § 3(c)(2)(B)."

In some cases Table B may note that EPA already possesses some or all of the product-specific data needed to evaluate your product; if that is the case, you must comply with FIFRA Section 3(c)(1)(D). See Section III of this guidance document.

VI. LABELING AND PACKAGING INFORMATION

Note: This section applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you must submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.1], as indicated by the following paragraphs of this section of the guidance document. The labeling must

be submitted within 6 months of your receipt of this guidance document.

If owners of currently registered products fail to submit revised labeling and packaging information complying with this section, EPA will issue a notice of intent to cancel the registration under FIFRA § 6(b)(1).

A. Label Contents

40 CFR Section 162.10 (Appendix VI-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix VI-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the

end of the label text. See Appendix VI-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net content must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix VI-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix VI-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix VI-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix VI-1. [40 CFR §162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements

grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various sized labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word As Required Minimum Type Size All Capitals	"Keep out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix VI-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix VI-1. [40 CFR §162.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned toxicity Category I on the basis of oral, inhalation or dermal toxicity, the word "Poison" shall appear on the label in red on a background of

distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix VI-1. (40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix VI-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or back) Panel for Additional Precautionary Statement" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix VI-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix VI-1. [40 CFR §162.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix VI-1. [40 CFR §162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. See Appendix VI-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix VI-3. The requirement is based on the results of the flash point determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flash point greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8 (c)(13)(ii) of Subpart D.

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii).

ii. There is no flash back; and

iii. The flash point of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the item "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazard of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." Appendix VI-1. [40 CFR §162.10(l)(2)(ii)]

Item 10A. STORAGE & DISPOSAL BLOCK - All labels are required to bear storage and disposal statements.

These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix VI-5 for the latest specific storage and disposal product labels.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix VI-5. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that

differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

VII. Instruction for Submission

All applications prepared in response to this Notice should be addressed as follows:

William H. Miller (16)
[Product Manager]
Phone No. (703) 557-2600
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, DC 20460

A. For each manufacturing-use product for which continued registration is desired:

1. Within 90 days from receipt of this document you must submit the "FIFRA Section (3)(c)(2)(B) Summary Sheet." Refer to Appendix IV-2(a) with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

a. "Application for Amended Pesticide Registration" (EPA Form 8570-1).

b. "Confidential Statement of Formula" (EPA Form 8570-4).

c. "Data Compensation Statement: Reregistration." Refer to Appendix III-1(a).

d. Product Specific Data Report (Appendix III-2).

e. Two copies of any required product-specific data.

f. Two copies of draft labeling, including the label and associated brochures. If the current labeling conforms to the requirements of this guidance document and the results of the short term data, the registrant can submit such labeling. Otherwise, the labeling should be in draft form. The draft labeling should be either type-written text on 8-1/2 x 11 inch paper or a mock-up of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front and side panels, and the intended type sizes of the text.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrants.

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

B. For each affected product for which continued registration is desired, within 90 days from receipt of this document submit:

1. The "FIFRA Section 3 (c)(2)(B) Summary Sheet" (Appendix IV-2) with appropriate attachments, and

2. The "Data Compensation Statement: Reregistration." Refer to Appendix III-1(b).

Appendix III-1(a)

DATA COMPENSATION STATEMENT: REREGISTRATION (MUPs)

EPA Reg. No.: _____

Product Name: _____

Applicant's Name & Address: _____

_____

_____

Date of application for reregistration: _____

Registration Standard for products containing: _____

Date Reregistration Guidance Document Issued: _____

In connection with applicant's application for reregistration under the Guidance Document identified above:

(A) Applicant offers to pay compensation to other persons to the extent required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

(B) Applicant understands and acknowledges that if EPA approves the application, the approval will be based solely on EPA's consideration of:

(1) All the generic data which, according to the Guidance Document identified above, were found relevant to EPA's evaluation of the registrability of applicant's product; and

(2) The product-specific data listed on the form entitled "Product-Specific Data Report" which is part of this application; and

(3) Applicant states that offers to pay compensation have been furnished to the persons and in the form specified by the Guidance Document identified above.

Dated: _____

Name of registrant's authorized representative: _____
(signature)

_____
(typed)

Appendix III-I(b)

DATA COMPENSATION STATEMENT: REREGISTRATION (End-Use Products)

EPA Reg. No.: _____

Product Name: _____

Applicant's Name & Address: _____

_____

_____

Date of application for reregistration: _____

Registration Standard for products containing: _____

Date registration Guidance Document Issued: _____

Registrant offers to pay compensation to other persons for the data listed in Table A to the extent required by sections 3(c)(1)(D) and 3 (c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registrant has furnished offers to pay compensation to the persons identified in Table A and in the form specified by the Guidance Document.

Dated: _____

Name of registrant's authorized representative: _____
(signature)

_____
(typed)

PRODUCT SPECIFIC DATA REPORT Appendix III-2

EPA Registration No._____

Guidance Document for _____
Date: _____

Registration Guideline No.	Name of Test	Test not required for my Product Listed Above (Check Below)	I am complying with Data Requirements by Citing MR ID #	I am complying with Data Requirements by Submitting Data (attached) (check box)	(For EPA Use Only) Accession Numbers Assigned
163-61-3	Product identity and disclosure of ingredients				
-4	Description of manufacturing process				
-5	Discussion on formation of unintentional ingredient				
-6	Declaration and certification of ingredient limits				
-7	Product analytical methods and data				
163-61-8(1)	Color				
-8(2)	Odor				
-8(3)	Melting point				
-8(4)	Solubility				
-8(5)	Stability				
-8(6)	Octanol/water partition coefficient				
-8(7)	Physical state				
-8(8)	Density or specific gravity				
-8(9)	Boiling point				
-8(10)	Vapor pressure				
-8(11)	pH				
-8(12)	Storage stability				
-8(13)	Flammability				
-8(14)	Oxidizing or reducing action				
-8(15)	Explosiveness				
-8(16)	Miscibility				
-8(17)	Viscosity				
-8(18)	Corrosion characteristics				
-8(19)	Dielectric breakdown voltage				
163-71-5(1)	Cage or pen field test				
-5(2)	Full-scale field test				
163-72-1	Fish acute LC_{50} - rainbow trout and bluegill				
-2	Acute toxicity to aquatic invertebrates				
-3	Acute toxicity to estuarine and marine organisms				
-6(a)(1)	Short term simulated field test				
-6(a)(2)	Long term simulated field test				
163-81-1	Acute oral toxicity				
-2	Acute dermal toxicity				
-3	Acute inhalation toxicity				
-4	Primary eye irritation				
-5	Primary dermal irritation				
-6	Dermal sensitization				

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier", or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standardq @nstitute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th 123456-Z; and the 27th, 123456-AA.

NUMERICAL CROSS REFERENCE FOR METHAMIDOPHOS

MRID #	CITATION
000014014	Stanley, C.W. (1971)
000014017	Chemagro Corporation (1971)
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000014019	Chemagro Corporation (1971)
000014021	Chevron Chemical Company (1970)
000014023	Hayman, E.L. (1969)
000014024	Chevron Chemical Company (1977)
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000014027	Leary, J.B. (1968)
000014028	Leary, J.B. (1969)
000014029	Leary, J.B. (1968)
000014030	Leary, J.B. (1970)
000014032	Leary, J.B. (1968)
000014033	Leary, J.B. (1968)
000014037	Chevron Chemical Company (1977)
000014044	Cavalli, R.D.; Hallesy, D.W. (1968)
000014045	Cavalli, R.D.; Hallesy, D.W. (1968)
000014047	Cavalli, R.D.; Hallesy, D.W. (1968)
000014048	Cavalli, R.D.; Hallesy, D.W. (1968)
000014049	Cavalli, R.D.; Hallesy, D.W. (1968)
000014051	Cavalli, R.D.; Hallesy, D.W. (1968)
000014063	Schoenig, G. (1968)
000014064	Jackson, G.L. (1968)
000014069	Mayberry, T.W.; Sakamoto, S.S.; Leary,J.B.; et al. (1969)
000014070	Cinereski, J.E.; Leary, J.B.; Sakamoto, S.S.; et al. (1969)
000014071	Cinereski, J.E.; Leary, J.B.; Mayberry, T.W.; et al. (1969)
000014072	Mayberry, T.W.; Sakamoto, S.S.; Leary, J.B.; et al. (1970)
000014073	Sakamoto, S.S.; Leary, J.B.; Klaich, M.; et al. (1969)
000014074	Sakamoto, S.S.; Kalens, K.J.; Witherspoon, B. (1969)
000014075	Gerber, C.E.; Leary, J.B.; Sakamoto, S.S. (1970)
000014076	Leary, J.B.; Tutass, H.O. (1968)
000014077	Chevron Chemical Company (1968)
000014081	Tutass, H.O. (1968)
000014085	Chevron Chemical Company (1968)
000014094	Fletcher, D. (1971)
000014095	Fletcher, D. (1971)
000014110	Wheeler, R.E. (1978)
000014113	Fink, R. (1977)
000014114	Beavers, J.B.; Fink, R. (1978)
000014119	Baychem Corporation (1973)
000014120	Baychem Corporation (1973)
000014121	Baychem Corporation (1973)
000014122	Baychem Corporation (1973)
000014123	Baychem Corporation (1973)
000014124	Baychem Corporation (1973)
000014125	Baychem Corporation (1973)
000014126	Baychem Corporation (1973)
000014127	Baychem Corporation (1973)

NUMERICAL CROSS REFERENCE FOR METHAMIDOPHOS

MRID #	CITATION
000014128	Baychem Corporation (1973)
000014129	Baychem Corporation (1973)
000014130	Baychem Corporation (1973)
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000014132	Baychem Corporation (1973)
000014133	Baychem Corporation (1973)
000014134	Baychem Corporation (1973)
000014135	Baychem Corporation (1973)
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000014139	Baychem Corporation (1973)
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000014153	Loser, E. (1970)
000014155	Loser, E. (1970)
000014220	Levy, J.E. (1979)
000014221	Rittenhouse, J.R. (1977)
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000014266	Chemonics Industries, Incorporated (1977)
000014269	Analytical Biochemistry Laboratories (1975)
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000014304	Lamb, D.W.; Burke, M.A. (1977)
000014305	Nelson, D.L.; Burke, M.A. (1977)
000014496	Tucker, B.V. (1972)
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000014555	Tucker, B.V. (1974)
000014991	Tucker, B.V. (1972)
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000029887	Thornton, J.S.; Hurley, J.B.; Obrist, J.J. (1976)
000041311	Nelson, D.L.; Roney, D.J. (1979)
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000041313	Nelson, D.L.; Burke, M.A.; Burnett, R.M. (1979)
000041315	Machemer, L.; Lorke, D. (1979)
000041317	Kruckenberg, S.M.; Fenwick, B.W.; Brown, S.M.; et al. (1979)
000041658	Nelson, D.L.; Burke, M.A.; Burnett, R.M. (1979)
005017379	Lubkowitz, J.A.; Horler, D.F.; Revilla, A.P.; Baruel, J.;
GS0043-001	Mobay Chemical Corp, (1981)
GS0043-002	Beavers, J.B., Fink, R. (1979)
GS0043-003	Zinkl, J.G., Roberts, R.B., Shea, P.J., Lasmanis, J. (1981)

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Registrations Under the Standard

000014269 Analytical Biochemistry Laboratories (1975) Chemagro Agricultural Division--Mobay Chemical Corporation Residue Experiment: 461-5725B-74D: Report No. 43802. (Unpublished study including report no. 43875, received Aug 24, 1978 under 3125-280; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:097318-D)

000014120 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Culiacan 1: Report No. 37306. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-E)

000014121 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Culiacan 1: Report No. 37307. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-F)

000014124 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Culiacan 1: Report No. 37310. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-I)

000014119 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Culiacan 2: Report No. 37305. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-D)

000014125 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Culiacan 2: Report No. 37311. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-J)

000014138 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Culiacan 2: Report No. 37389. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-W)

000014140 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Culiacan 2: Report No. 37391. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-Y)

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000014122 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 1: Report No. 37308. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-G)

000014126 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 1: Report No. 37312. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-K)

000014128 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 1: Report No. 37314. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-M)

000014130 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 1: Report No. 37316. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-O)

000014134 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 1: Report No. 37320. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-S)

000014123 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 2: Report No. 37309. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-H)

000014127 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 2: Report No. 37313. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-L)

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000014129 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 2: Report No. 37315. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-N)

000014131 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 2: Report No. 37317. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-P)

000014132 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 2: Report No. 37318. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-Q)

000014133 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 2: Report No. 37319. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-R)

000014135 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: Los Mochis 2: Report No. 37321. Rev. (Unpublished study received Jul 20, 1973 under 4F1424; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:093798-T)

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GS0043-002 Beavers, J.B.; Fink,R. (1979) Eight-day Dietary LC_{50}-Bobwhite Quail, Technical Monitor, Final Report No. 68259 (Unpublished Study received Jan. 26, 1982, under 239-2404; prepared by Wildlife International, LTD., submitted by Chevron Chemical Co., Richmond CA; CDL: 246656)

000014049 Cavalli, R.D.; Hallesy, D.W. (1968) Acute Dermal Toxicity of Monitor Technical: SOCO 30/I:121-8. (Unpublished study received Mar 5, 1970 under 0F0956; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:093265-G)

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000014019 Chemagro Corporation (1971) Recovery of Monitor® from Bass and Rainbow Trout, Confirmatory Column: Report No. 30977. (Unpublished study received on unknown date under 0F0956; submitted by Chevron Chemical Co., [illegible]mond, Calif.; CDL:093266-K)

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000014266 Chemonics Industries, Incorporated (1977) Chemagro Agricultural Division—Mobay Chemical Corporation Residue Experiment: 263-5736-76H: Report No. 53030. (Unpublished study received Aug 24, 1978 under 3125-280; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, Mo.; CDL:097317-D)

000014518 Cheng, H.M. (1974) Characterization of 14C in Liver and Urine from Rats Treated Orally with S-Methyl-14C-Orthene or S-Methyl-14C-Ortho 9006. (Unpublished study received Nov 10, 1976 under 239-2418; submitted by Chevron Chemical Co., Richmond, Calif.; CDL: 095570-L)

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Appendix IV-2(a)

FIFRA §3(C)(2)(B) SUMMARY SHEET

EPA Registration No.: _____
Product Name: _____
Applicant's Name: _____
Date Guidance Document Issued: _____

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(c)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

1. ☐ I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

2. ☐ I have entered into an agreement with one or more other registrants under FIFRA § 3(c)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by (name of other registrant).

3. ☐ I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

4. ☐ I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

5. ☐ I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

Dated: _____

Registrant's authorized representative:

_____
(signature)

_____
(typed)

Appendix IV-3

CERTIFICATION OF ATTEMPT TO ENTER
INTO AN AGREEMENT WITH OTHER REGISTRANTS
FOR DEVELOPMENT OF DATA
(TO QUALIFY, CERTIFY ALL FOUR ITEMS)

(1) I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document dated _____ to submit data concerning the active ingredient _____:

Name of Firm — EPA Company Number

(This firm or group of firms is referred to below as "my firm".)

(2) My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

(3) My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Firm — Date of Offer

However, none of those firm(s) accepted my offer.

(4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

Dated: _____

_____
(Signature)

_____
(Typed)

cc: A copy of the offer(s) is attached.

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide producer shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of content.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement.*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients, and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of

the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22–25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups: those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg.
Inhalation LC$_{50}$	Up to and including .2 mg/l/4hr.	From .2 thru 2 mg/l/4hr.	From 2 thru 20 mg/l/4hr.	Greater than 20 mg/l/4hr.
Dermal LD$_{50}$	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.

76

[illegible]	Toxicity categories			
	I	II	III	IV
[illegible]	Corrosive (irreversible effects not manifested within 7 days).	Corrosive (severe irritation at 72 hours, corneal involvement or irritation clearing in 7 days).	No corneal involvement or irritation clearing in 7 days.	No irritation.
[illegible]	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word.*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "Keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment.*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label (area of principal display panel)	Required signal word, at minimum	"Keep out of reach of Children"
	Points	Points
5 sq. in. or less	6	6
Above 5 to 10 sq. in.	10	6
Above 10 to 15 sq. in.	12	8
Above 15 to 30 sq. in.	14	10
Over 30 sq. in.	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Oral, inhalation, or dermal toxicity	Skin and eye toxic effects
I	[illegible]	Corrosive, causes eye and skin damage [or use on animal]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed, absorbed through skin, or inhaled. [Antidotes, first aid statement required.]
II	May be fatal if swallowed. Corrosive or absorbed through the skin. Do not breathe vapors (dust or spray mist). Do not get in eyes, on skin, or on clothing. [Antidotes, first aid statement required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing, [wash if contacted]. [Antidotes, first aid statement required.]
III	Harmful if swallowed. Corrosive or absorbed through the skin. Avoid breathing vapors (dust or spray mist). Avoid contact with skin [and/or on clothing]. [Antidotes, first aid statement required.]	Avoid contact with eyes, skin or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum size as required for the child hazard warning (See Table in § 162.10(h)(1)(iv)).

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1978, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for

use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(ii) *Advertising* [Reserved]

[40 FR 28282, July 3, 1975; 40 FR 32008, Aug. 1, 1975; 40 FR 34877, Aug. 21, 1975, as amended at 43 FR 5736, Feb. 3, 1978]

TABLE D

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product Name	All Products	Front panel	Center front panel	
2	Company Name and Address	All Products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for..." "Distributed by...," etc.
3	Net Contents	All Products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S units.
4	EPA Est. No.	All Products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All Products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients Statement	All Products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/Gallon Statement	Liquid products where dosage given as lbs ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front Panel Precautionary Statements	All Products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.

TABLE B

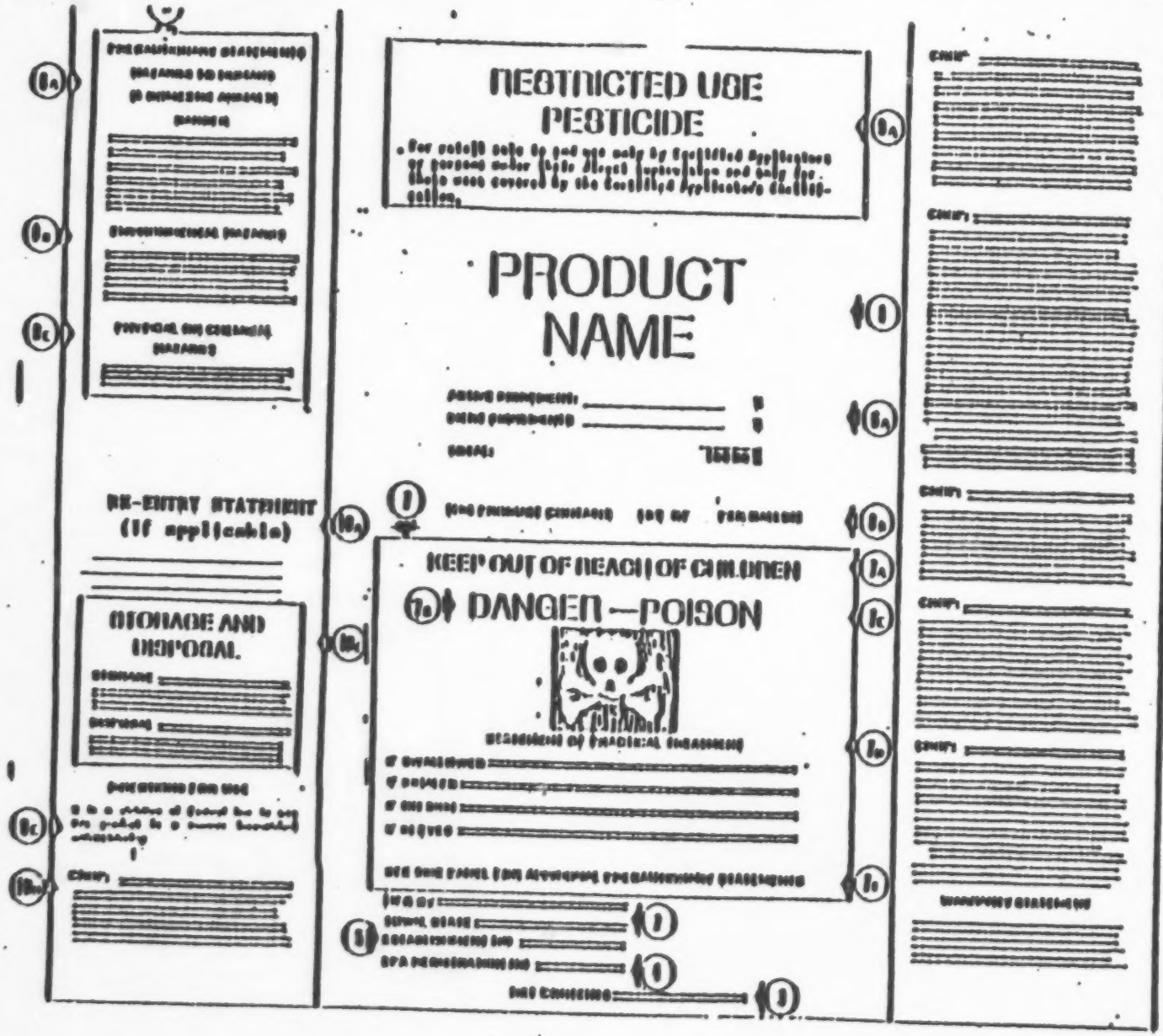
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
7A	Keep Out of Reach of Children (Child Hazard Warning)	All Products	Front panel	Above signal word	Note type size requirements.
7B	Signal Word	All Products	Front panel	Immediately below Child Hazard Warning	Note type size requirements.
7C	Skull & Crossbones and word "POISON" (in red)	All products which are Category I based on oral, dermal or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used, Others: Grouped with side panel precautionary statements	Front panel for all	
7E	Referral Statement	All products where precautionary labeling appears on other than front panel	Front panel		

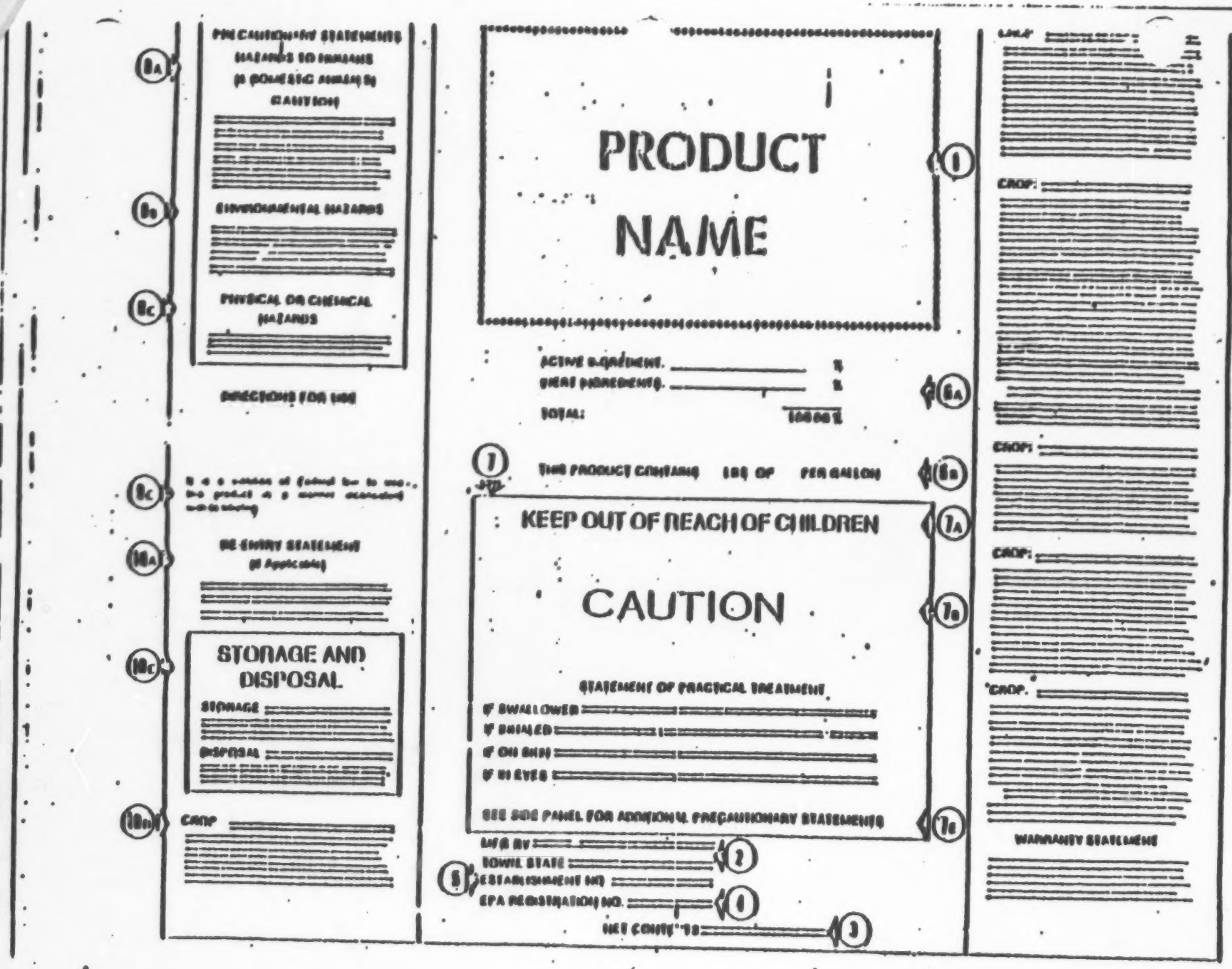
TABLE F-1

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL REQUIRED	PREFERRED	COMMENTS
8	Side/Back Panel Precautionary Statements	All Products	None	Top or side of back panel preceding Directions for Use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to Humans and Domestic Animals	All Products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental Hazards	All Products	None	Same as above	Environmental hazards include bee caution where applicable.
8C	Physical or Chemical Hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted Block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse Statement	All products	Immediately following Statement of Classification or ahead of Directions for Use		
10A	Re-entry Statement	All Cholinesterase Inhibitors	In the Directions for Use	Immediately after Misuse Statement	

TABLE F-2

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
16C	Storage and Disposal Block	All products	In the Directions for Use	Immediately before specific directions for use or at the end of Directions for Use	Must be grouped together, and preferably blocked. Heading must be same type size as Child Hazard Warning.
16D U.S.	Directions for Use	All products	None	None	May be in metric units as well as U.S. units.


RESTRICTED USE PESTICIDE
PRODUCT NAME
KEEP OUT OF REACH OF CHILDREN
DANGER—POISON
STORAGE AND DISPOSAL
RE-ENTRY STATEMENT (If applicable)


8A
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
CAUTION
8B
ENVIRONMENTAL HAZARDS
8C
PHYSICAL OR CHEMICAL
HAZARDS
DIRECTIONS FOR USE
8C
10A
RE-ENTRY STATEMENT
(If Applicable)
10C
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
10D
CROP
PRODUCT
NAME
1
ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %
6A
7
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
KEEP OUT OF REACH OF CHILDREN
7A
CAUTION
7B
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7C
MFG BY
2
TOWN, STATE
5
ESTABLISHMENT NO.
EPA REGISTRATION NO.
4
NET CONTENTS
3
LABEL
CROP:
CROP:
CROP:
CROP:
WARRANTY STATEMENT

Physical - Chemical Hazards

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flash points at or below 20°F; or if there is a flashback at any valve opening	Extremely Flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20° and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS.	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperature above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Above 150°F	None Required

PROPOSED DISPOSAL STATEMENTS FOR PESTICIDES

PESTICIDE DISPOSAL (all except household)

Pesticide, spray mixture or rinsate that cannot be used according to label instructions must be disposed of according to Federal, State or local procedures under the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL

1. Household (all)

Do not reuse empty container (bottle, can, bucket).
Wrap (container) and put in trash collection.

2. Metal (all sizes)

Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other approved State and local procedures.

3. Plastic (all)

Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if permitted by State and local authorities.

4. Glass (all)

Triple rinse (or equivalent) and dispose of in a sanitary landfill or by other approved State and local procedures.

5. Fiber drums with liners

Dispose of liners according to approved Federal, State or local procedures under the Resource Conservation and Recovery Act. If container cannot be reused*, dispose of in a sanitary landfill or by incineration if permitted by State and local authorities.

*Manufacturer should replace this phrase with one indicating whether and how fiber container may be reused.